

**IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION**

HI-TECH PHARMACEUTICALS, INC., a)
Georgia corporation,)

Plaintiff,)

v.)

DYNAMIC SPORTS NUTRITION, LLC)
d/b/a ANABOLIC RESEARCH,)
a TEXAS Limited Liability Company;)
PBB TRADEMARK HOLDINGS, LLC,)
a Texas Limited Liability Company, and)
BRIAN CLAPP, an individual,)

Defendants.)

Case No. 1:16-cv-00949-MHC

**HI-TECH PHARMACEUTICALS, INC.'S RESPONSE
IN OPPOSITION TO DEFENDANTS'
MOTION FOR SUMMARY JUDGMENT**

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Comes now, Hi-Tech Pharmaceuticals, Inc. (“Hi-Tech”), and hereby submits this Opposition to Defendants’ Motion for Summary Judgment.

INTRODUCTION

Defendants’ Motion pretends as though the record in this case has not developed since this Court’s Order on Hi-Tech’s Second Application for Temporary Restraining Order. For instance, Defendants utterly ignore unrebutted evidence that they intentionally and willfully sought to profit off of Hi-Tech’s brand recognition while deceptively distracting Hi-Tech; they ignore unrebutted evidence that consumers are confused between Hi-Tech’s DIANABOL[®] and Defendants’ D-ANABOL 25; and they ignore unrebutted evidence that their product claims are false and misleading. Instead of attempting to address this evidence, Defendants argue Hi-Tech is not entitled to relief based upon irrelevant and inadmissible evidence concerning other proceedings and absurd allegations of unlawful conduct. Indeed, Defendants concern themselves with trace amounts of androstenedione, a natural substance common in animal food products and the water supply. Simply put, the relevant, admissible evidence shows that there are genuine issues of material fact that preclude summary judgment in favor of Defendants.

ARGUMENT AND CITATION OF AUTHORITY

I. DEFENDANTS ARE NOT ENTITLED TO SUMMARY JUDGMENT ON HI-TECH’S TRADEMARK-RELATED CLAIMS.

A. Hi-Tech Has Not Engaged in Unlawful Activities Barring Its Enforcement of the DIANABOL[®] Trademark.

1. The Eleventh Circuit Has Appropriately Declined to Adopt the “Unlawful Use” Doctrine.

The unlawful use doctrine provides that a plaintiff’s trademark claims may be barred if the plaintiff’s use of the mark violated the law. *FN Herstal SA v. Clyde Armory, Inc.*, 838 F.3d 1071, 1087 (11th Cir. 2016).

The party asserting the defense must establish that it applies by clear and convincing evidence. Not every violation, however, will be sufficient to justify denial of trademark protection based on unlawful use. There must be a nexus between the use of the mark and the violation, and the violation must be material. To be material, the violation must be of such gravity and significance that the usage must be considered unlawful—so tainted that, as a matter of law, it could create no trademark rights. This Court has not adopted the unlawful use doctrine.

Id. (internal punctuation and citations omitted). Further, as stated in the *FN Herstal* case, the unlawful use doctrine requires that the unlawfulness be based on a previous determination by “a court or government agency having competent jurisdiction under the statute involved” or “a per se violation of a statute regulating the sale of a party’s goods.” *Id.* There has been no filing by a court or government agency that Hi-Tech’s Dianabol[®] supplement is in violation of a statute or regulation.

As acknowledged by Defendants, only a small minority of courts have adopted the unlawful use doctrine. Doc. 160 at p. 11. Indeed, “[t]he ‘unlawful use doctrine’ appears almost exclusively in the administrative setting, originating in

United States Trademark Trial and Appeal Board (‘TTAB’) proceedings to oppose trademark applications or cancel registrations.” *FN Herstal*, 838 F.3d at 1086. The fact that only a small proportion of courts have adopted the unlawful use doctrine, and that the Eleventh Circuit declined to do so when presented with the opportunity, is not surprising. Application of the doctrine with respect to alleged violations of certain federal laws essentially permits private enforcement of a federal statute where none is allowed. Defendants in this case argue that Hi-Tech’s claims should be barred for alleged violations of the Drug Abuse Prevention and Control Act (“DAPCA”), the Food, Drug and Cosmetic Act (“FDCA”), and the Code of Federal Regulations. Doc. 160 at 12-14.

21 U.S.C. § 871, however, reserves enforcement of the DAPCA for the Attorney General and the Department of Justice, and 21 U.S.C. § 337(a) restricts enforcement of the FDCA to suits by the United States. Additionally, Title 21 of the Code of Federal Regulations is “applicable to regulatory enforcement actions *initiated by the Food and Drug Administration ...*” 21 C.F.R. § 7.1 (emphasis added). Given the exclusive nature of this authority, courts have repeatedly refused to allow defendants in trademark suits to assert violations of such statutes as an affirmative defense. *See, e.g., Inmuno Vital, Inc. v. Golden Sun, Inc.*, 49 F.Supp.2d 1344, 1359 (S.D.Fla. 1997); *Healthpoint, Ltd. v. Ethex Corp.*, 273 F.Supp.2d 817,

849 (W.D.Tex. 2001); *Pediamed Pharm., Inc. v. Breckenridge Pharm., Inc.*, 419 F.Supp.2d 715, 727 (D.Md. 2006).

The Court should be especially wary of allowing Defendants to encroach upon the exclusive authority of the federal government in this case. As set forth below, Defendants have not established a violation or material violation of any statute or regulation by clear and convincing evidence.

2. Defendants' Arguments Ignore Material Evidence.

In arguing that Hi-Tech's DIANABOL[®] product violates 21 U.S.C. § 841 and 21 U.S.C. §§ 331 and 343, Defendants ignore numerous disputed material facts.

First, Defendants argue that the label for Hi-Tech's Dianabol[®] supplement label fails to disclose DHEA as an ingredient in violation of federal law, Doc. 160 at p. 14, but DHEA is in fact listed on the label. Review of the label attached to Defendants' Motion reveals that among the product's ingredients are "Dehydroepiandrosterone Acetate," "Dehydroepiandrosterone Decaonate," and "7-Keto-DHEA." Doc. 160-16. These are all forms of DHEA. Exh. 1 at p. 9, Table 1. DHEA is, therefore, disclosed as an ingredient.

Second, Defendants ignore that the accuracy and level of certainty in their testing is questionable, and that their detection of DHT, albeit in trace amounts, is inconsistent with other evidence on record. *Id.* at ¶¶ 24-59, 64. Specifically,

Defendants' detection of DHT is inconsistent with testing performed by Hi-Tech on DIANABOL[®] and raw ingredients, as well as Hi-Tech's batch records, which show that no DHT was added to the product. *Id.* at ¶ 64.

Third, Defendants ignore the source of the androstenedione detected, which was the synthesis of dehydroepiandrosterone ("DHEA"). DHEA is an ingredient in Hi-Tech's DIANABOL[®] product, Defendants' Winn 50 product, and various other dietary supplement products on the market. Doc. 160-16; Exh. 2; Exh. 3. DHEA is a legal dietary supplement ingredient. 21 U.S.C. § 802(41)(A) (expressly excluding DHEA from the definition of "anabolic steroid"). DHEA is derived from androstenedione, such that trace amounts of androstenedione remain in the DHEA raw material following its conversion to DHEA.¹ Exh. 1 at ¶¶ 60-63. Hi-Tech has confirmed DHEA as the source of the androstenedione detected in the DIANABOL[®] supplement through testing of DHEA raw materials, and testing showing detectable amounts of androstenedione in other DHEA-containing products on the market, to include Defendants Winn 50. *Id.* at ¶¶ 62, 63; Exh. 3; Exh. 4; Exh. 5. Indeed, testing of DHEA products from 12 well-known brands all revealed trace amounts of androstenedione. Exh. 3. Further, the DHEA raw materials used by Hi-Tech were manufactured by a third-party, Exh. 1 at ¶ 60, and there is no evidence that Hi-Tech

¹ The FDA permits synthesized dietary supplement ingredients. EXHIBIT 6 at ¶ 14.

was aware that androstenedione was used to create DHEA, or that androstenedione would be present in trace amounts in synthesized DHEA.

Fourth, Defendants ignore the miniscule levels of the androstenedione and DHT detected by their testing. According to the testing, a daily dose of Dianabol[®] (3 tablets) would result in the consumption of only 24 micrograms, or 24 *millionths* of a gram, of androstenedione. *Id.* at ¶ 66. Similarly, at the DHT level cited by Defendants' testing, one would absorb only 5.54 micrograms, or 5.45 *millionths* of a gram, by way of a daily dose of the Dianabol[®] supplement. *Id.* at ¶ 70. When compared to the total weight of the ingredient blend of a daily dose of the Dianabol[®] supplement, which is 1,725 milligrams, or 1.725 grams, Doc. 160-16, the alleged trace amounts of androstenedione and DHT amount to but 0.001688 percent (0.00002954 grams/1.75 grams) of the total blend.

Fifth, Defendants ignore that, given these minuscule amounts, to the extent androstenedione or DHT is present in Dianabol[®], it is not in a sufficient quantity to cause a physiological effect creating any risk to consumers. *Id.* at ¶¶ 65-72. The amount of androstenedione detected by Defendants is 12,500-fold lower than what has been found to have significant effects on serum testosterone, and the amount of DHT detected by Defendants is 20,000-fold lower than that used by scientists in an effort to identify measurable indicators of DHT. *Id.* at ¶¶ 68, 71.

3. Even if the “Unlawful Use” Doctrine Did Apply, It Would Not Bar Hi-Tech’s Claims Because There Has Been No Violation of the Law, Much Less A “Material” Violation of the Law.

Contrary to what Defendants imply, the law is not deaf to the reality that foods² and drugs frequently contain miniscule and harmless amounts of impurities. *United States v. Articles ... Provimi*, 425 F.Supp. 228, 229 (D.N.J. 1977) (“Whether an article in interstate commerce is a food or a drug, the court is well aware that no named substance, whatever it may be, can be ‘absolutely pure.’”). The Food and Drug Administration (“FDA”) has also recognized that “it is not possible to produce food or food ingredients that are entirely free from contamination by foreign substances or impurities.” *Poisonous or Deleterious Substances*, Food and Drug Admin., 42 Fed. Reg. 190 (Sept. 30, 1977).

The FDCA is explicit in its acknowledgement of these circumstances. For instance, 21 U.S.C. § 342(A), defining “adulterated food,” provides that:

A food shall be deemed to be adulterated ... [i]f it bears or contains any poisonous or deleterious substance *which may render it injurious to health*; but in case the substance is not an added substance such food shall *not* be considered adulterated under this clause *if the quantity of such substance in such food does not ordinarily render it injurious to health* ...

² Dietary supplements are considered “foods” under the FDCA and regulated as such. 21 U.S.C. § 321(ff).

Id. at § 342(A)(1) (emphasis added). The United States Supreme Court has interpreted the “which may render [it] injurious to health” language as providing that the presence of poisonous substances to food in such minute quantities that the health of consumers cannot be injured is not condemned. *United States v. Lexington Mill & Elevator Co.*, 232 U.S. 399, 409-10 (U.S. 1914); *Young v. Cmty. Nutrition Inst.*, 476 U.S. 974, 983 (1986).

The FDCA also acknowledges the acceptability of harmless amounts of “poisonous or deleterious” substances present in food. In 21 U.S.C. § 346, the FDA is granted the authority to set tolerance levels for such substances, “tak[ing] into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.”³ Thus, Defendants cannot show by clear and convincing evidence that the trace amounts alleged constitute a violation of 21 U.S.C. §§ 342 and 346.

³ The FDA is not required to set tolerance levels for substances. *Young*, 476 U.S. at 981-83. The FDA has not set a tolerance level for androstenedione or DHT. Notably, “the Act does provide that when a tolerance level has been set and a food contains an added harmful substance in a quantity below the tolerance level, the food is legally not adulterated. But one cannot logically draw from this premise, or from the Act, the [] conclusion that food containing substances *not* subject to a tolerance level *must be* deemed adulterated.” *Id.* at 982 (emphasis original).

As for labeling, 21 U.S.C. § 343(q)(5)(F) allows dietary supplement products to comply with labeling requirements “in a manner which is appropriate for the product,” and provides that dietary ingredients “not present in significant amounts” do not need to be listed on the label. *Id.* at § 343(q)(5)(i); *see also id.* at § 343(q)(5)(C) (nutrients in “insignificant amounts” may not need to be identified on a label). And the definition of “drug” accounts for the intended purpose of the product. *Id.* at § 321(g)(1).

Additionally, the long-recognized “*de minimus*” doctrine in food and drug law mitigates against unjustifiably harsh consequences of an overly literal interpretation of FDA regulations. *United States v. Undetermined Quantities of Various Articles ... of Proplast II or Proplast HA*, 800 F.Supp. 499, 503 (S.D.Tex. 1992). This equitable doctrine recognizes that the law does not concern itself with all technical “violations” of the FDCA. *See 338 Cartons, More or Less, of Butter v. United States*, 165 F.2d 728, 731 (4th Cir. 1948) (“The courts have recognized that adulteration of foodstuffs may be so slight as to come under the maxim *de minimis non curat lex*.”); *United States v. 900 Cases Peaches*, 390 F.Supp. 1006, 1010 (D.C.N.Y. 1975) (stating that strict enforcement “would set a standard which ‘would ban all processed food from interstate commerce’”). *Adver. to Women, Inc. v. Gianni Versace S.p.A.*, 2000 WL 1230461, at *5 (N.D.Ill. 2000) (declining to cancel a

trademark registration where the alleged misbranding was not material and did not raise “serious consumer protection concerns”); *see also Gibbs Patrick Farms, Inc. v. Syngenta Seeds, Inc.*, 2008 WL 822522, at *18 (M.D.Ga. 2008) (“A basic concept of toxicology [] is that individuals can be safely exposed to toxic substances up to a threshold level.”); *United States v. 1,200 Cans Pasteurized Whole Eggs*, 399 F.Supp. 131, 137 & 141 (N.D.Ga. 1972) (finding that a “reasonable interpretation” of the FDCA is appropriate, and that where the FDA has not established measurable tolerances for contaminants in food, “the question must be determined by the totality of the circumstances as revealed by the evidence”).

As for 21 U.S.C. § 841, it also should not be applied so as generate an “absurd result.” *See Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 564, 575 (1982). Such a result can occur under a literal reading of drug statutes where a barely detectable amount of a controlled substance is at issue. *See, e.g., United States v. Chin Chong*, 990 F.Supp.2d 320, 322-23 (E.D.N.Y. 2014) (noting that “90% of the paper currency in the United States is contaminated with a ‘detectable amount’ of cocaine”). Such an “absurd result” would occur in this case if Hi-Tech’s trademark rights were held to be unenforceable based on the alleged presence of trace amounts of androstenedione and DHT. This is especially true in light of the fact that the trace

amount of androstenedione constituted a manufacturing byproduct of a raw material manufactured by a third-party. Exh. 1 at ¶ 60.

Finally, Hi-Tech's lack of prior knowledge, the miniscule nature of the alleged trace amounts of androstenedione and DHT, and the manufacturing process as the source of the androstenedione create a genuine issue of material fact as to whether Hi-Tech had the requisite intent to criminally violate 21 U.S.C. §§ 331, 343, and 841. Simply put, Hi-Tech (like Defendants and the many others whose DHEA products were also found to contain androstenedione) had no motive to include the trace amounts alleged. Defendants' motion presumes intent on the part of Hi-Tech but fails to identify any evidence that Hi-Tech knowingly and intentionally added the trace amounts of androstenedione and DHT alleged.

In sum, Defendants have failed to demonstrate a per se violation, much less a "grave and significant" violation as required by the unlawful use doctrine. *FN Herstal*, 838 F.3d at 1087. The clear and convincing evidence standard requires that the evidence "leave no room for doubt, speculation, surmise, or interpretation." *FN Herstal, SA v. Clyde Armory, Inc.*, 2015 WL 196208, at *9 (M.D.Ga. Jan. 8, 2015). Defendants fall short of meeting this burden.

B. The "Unclean Hands" Doctrine Does Not Bar Hi-Tech's Claims.

To prevail on the affirmative defense of unclean hands, a party must demonstrate that: (1) the plaintiff's wrongdoing is "directly related to the claim against which it is asserted," and (2) the defendant was personally injured by the plaintiff's conduct. *Bailey v. TitleMax of Georgia, Inc.*, 776 F.3d 797, 801 (11th Cir. 2015). Defendants do not even set forth the elements of the defense in their brief, much less establish that the elements are met in this case.

For instance, Defendants do not argue that they were personally injured by the conduct set forth in their brief. Doc. 160 at pp. 14-15. There is also no evidence on record to that effect. The unclean hands defense must fail for this reason alone.

Additionally, as for the alleged wrongdoing, Defendants must establish each of the elements of a false advertising claim⁴ to establish unclean hands based upon false advertising. *Wika Instrument I, LP v. Ashcroft, Inc.*, 2015 WL 11199059, at *8 (N.D.Ga. July 10, 2015) ("[The defendant] merely presumes that [the plaintiff] has engaged in false advertising without addressing each of the elements of a false advertising claim under the Lanham Act. [The defendant's] belief that [the plaintiff]

⁴ The elements of a false advertising claim are (1) the advertisements of the opposing party were false or misleading; (2) the advertisements deceived, or had the capacity to deceive, consumers; (3) the deception had a material effect on purchasing decisions; (4) the misrepresented product or service affected interstate commerce; and (5) the movant has been – or is likely to be – injured as a result of the false advertising. *Hickson Corp. v. Northern Crossarm Co., Inc.*, 357 F.3d 1256, 1260 (11th Cir. 2004).

engaged in false advertising is not sufficient to establish unclean hands on the part of [the plaintiff].”); *Immuno Vital*, 49 F.Supp.2d at 1358-59.

Defendants assert that Hi-Tech’s use of the DIANABOL[®] trademark “inherently mislead consumers regarding the nature of the product,” and that a single alleged ad⁵ “fueled that consumer confusion.” Doc. 160, p. 15. However, there is no evidence on record to support Defendants’ conclusory assertions. And, Defendants fail to even address other elements of a false advertising claim against Hi-Tech, much less show an absence of disputed facts regarding such allegations.

Defendants attempt to rely on other legal proceedings is similarly unavailing because the proceedings are not related to Hi-Tech’s Dianabol[®] supplement or trademark, much less “directly related” to them. It is well established that the doctrine of unclean hands only applies where the acts of the plaintiff have an

⁵ It is Hi-Tech’s position that the advertisements contained in Doc. 160-4 apparently came from a source known to have fabricated documents in the past as to Hi-Tech, and that Defendants would not be able to authenticate these ads at trial. While this Court previously cited similar language in an advertisement attached to the USPTO’s denial of Defendant’s trademark application, Doc. 82 at 25 n. 9, this ad was from the website of a third-party, not Hi-Tech. Exh. 7 at pp. 10-11.

Hi-Tech further notes that the alleged ad at Doc. 160-4 at 1 appears to cut off language stating that “The new king of bodybuilding supplementation *is no longer a [drug]*.” (Emphasis added). Defendants also ignore that the ads in their exhibit repeatedly and prominently identify the primary active constituent in the Dianabol supplement as being Belizean Man Vine, state that the supplement contains “herbal extracts,” and identify the product as a “supplement.” Doc. 160-4.

“immediate and necessary relation” to the remedy sought in the current litigation. *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240, 245 (1933). Indeed, “[t]he maxim of unclean hands is not applied where plaintiff’s misconduct is not directly related to the merits of the controversy between the parties, but only where the wrongful acts ‘in some measure affect the equitable relations between the parties in respect of something brought before the court for adjudication.’” *Mitchell Bros. Film Group v. Cinema Adult Theater*, 604 F.2d 852, 863 (5th Cir. 1979) (quoting *Keystone*, 290 U.S. at 245). However, none of the proceedings cited by Defendants bear the remotest of relations to Hi-Tech’s Dianabol[®] supplement or trademark, such that these instances cannot be properly relied upon to establish an unclean hands defense. *See, e.g., Hi-Tech Pharm., Inc. v. Demelo*, 2009 WL 901156, at *9 (N.D.Ga. 2009) (denying defendant’s motion for summary judgment against Hi-Tech’s trademark infringement claims where the defendant’s unclean hands defense relied upon the FTC case and prior convictions); *see also Mitchell*, 604 F.2d at 863 (“The doctrine of unclean hands does not purport to search out or deal with the general moral attributes or standing of a litigant.”)

Lastly, the alleged trace amounts of androstenedione and DHT being detected in certain product samples do not support a finding of unclean hands. Defendants’

argument to that effect is a simply a repackaging of the “unlawful use” doctrine addressed above. As explained by this Court regarding the unclean hands defense:

The courts [] consider the culpability of the conduct. *Shatel Corp.*, 49 F. Supp. 2d 1344 (concluding that defense of unclean hands did not apply where mistake was inadvertent); *Ford Motor Co. v. O.E. Wheel Distribs, LLC*, [868 F.Supp.2d 1350] (M.D. Fla. 2012) (“[I]n trademark infringement actions, courts have required clear, convincing evidence of egregious misconduct before invoking the doctrine of unclean hands.”) (internal quotation marks omitted); *Pedinol Pharmacal, Inc. v. Rising Pharm., Inc.*, 570 F. Supp. 2d 498, 505 (E.D.N.Y. 2008) (requiring “truly unconscionable and brazen behavior”) (internal quotation marks omitted).

DS Waters of America, Inc. v. Fontis Water, Inc., 2012 WL 12873771, at *24 (N.D.Ga. Sept. 13, 2012). There is no such culpable conduct on the part of Hi-Tech. Hi-Tech did not know that a trace amount of androstenedione might remain in the product as a result of the formulation process for a raw material ingredient prepared by a third-party; Hi-Tech did not intentionally add androstenedione or DHT to its product; and the trace amounts detected are not in a saleable, usable, or harmful amounts. *See* Exh. 1 at ¶¶ 60-73. Hi-Tech’s conduct therefore does not rise to the culpability and egregiousness contemplated by the unclean hands defense.

C. Hi-Tech’s DIANABOL[®] Trademark is Not Generic.

Because Hi-Tech’s DIANABOL[®] trademark is a registered trademark, Defendants must overcome the presumption that the mark is not generic. *In re Cordua Rest., Inc.*, 823 F.3d 594, 600 (Fed. Cir. 2016). This Court has stated:

A generic name refers to ‘*a particular genus or class of which an individual article or service is but a member.*’ It is the ‘term by which the product or service itself is commonly known’ and depicts the product or service as a whole, rather than any particular feature, quality, or characteristic of the whole. ‘A word may be generic of some things and not of others: ‘ivory’ is generic of elephant tusks but arbitrary as applied to soap.’

ITT Corp. v. Xylem Group, LLC, 963 F.Supp.2d 1309, 1320 (N.D.Ga. 2013) (emphasis added, internal citation omitted). Thus, a term may be generic when it is “commonly used as the name or description *of a kind of good.*” *Schmidt v. Honeysweet Hams, Inc.*, 656 F.Supp. 92, 95 (N.D.Ga. 1986) (emphasis original). The Lanham Act permits cancellation when a “registered mark becomes the generic name for the goods or services ... *for which it is registered....*” 15 U.S.C. § 1064(3) (emphasis added); *see also In re Cordua*, 823 F.3d at 602 (A proper genericness inquiry focuses on the identification of the goods set forth in the registration).

Finding that a trademark is generic and pitching it into the public domain is a “fateful step ordinarily [] not taken until the trademark has gone so far toward becoming the exclusive descriptor of the product that sellers of competing brands cannot compete effectively without using the name to designate the product they are selling,” *Ty, Inc.*, 353 F.3d at 531, and Defendants have not offered sufficient evidence for the Court to take that step in this case. In this case, when ruling on Hi-Tech’s Second Application for Temporary Restraining Order, the Court found that

there was “a disputed issue of material fact as to whether Plaintiff’s trademark is generic ...” Doc. 82 at p. 16. This disputed issue of material fact remains.

Hi-Tech’s DIANABOL[®] trademark is registered for the following class of goods: “dietary supplements, excluding anabolic steroids.” Doc. 160-15 at p. 1. The genericness inquiry should therefore focus on this class of goods and not a broader class of goods that includes anabolic steroids. *See Carter Products, Inc. v. Fleetwood Co.*, 333 F.2d 464, 466 (C.A.Ill. 1964) (finding that for trademark purposes, a drug and dietary supplement “are not competitive and the means for distributing and promoting them are substantially different”); *Pharmacia & Upjohn Co., v. Generation Health d/b/a Pharmanex, Inc.*, 1997 WL 750605, at * (W.D.Mi. 1997) (finding that for trademark purposes, drugs and dietary supplements were “not unrelated,” but “not directly competing products”).

Evidence on genericness may include competitors' use, plaintiff's use, dictionary definitions, media usage, testimony of persons in the trade, and consumer surveys. *Hasbro, Inc. v. MGA Entm't, Inc.*, 497 F.Supp.2d 337, 342 (D.R.I. 2007).

First, outside of a handful of apparent infringers identified by Clapp in 2012, Defendants have proffered no evidence of competitors’ use of Hi-Tech’s DIANABOL[®] trademark. Exh. 8. This limited third-party use alleged by Defendants is insufficient evidence upon which to base a finding of genericness. *See, e.g.*,

Florida Int’l Univ. Bd. of Trustees v. Florida Nat’l Univ., Inc., 830 F.3d 1242, 1257–58 (11th Cir. 2016) (collecting cases, eight to 27 instances of third-party use may *diminish* strength of mark, but did not result in findings of genericness). Further, “unauthorized use of a mark does not necessarily render a mark weak. The proper inquiry is whether the third party use *significantly* diminishes the public's perception that the mark identifies services connected with the owner.” *Trilink Saw Chain, LLC v. Blount, Inc.*, 583 F.Supp.2d 1293, 1312 (N.D.Ga. 2008) (emphasis original).

As for media usage, the evidence marshalled by Defendants falls far short of eliminating any genuine issue of material fact with respect to whether “Dianabol” or “dianabol” is generic for a genus or class of goods. At most, Defendants identify evidence that the word was associated with methandrostenolone – a single anabolic steroid – but not steroids or muscle building products generally. In support of their motion, Defendants attached 24 publications which refer to “Dianabol” or “dianabol.” Doc. 160-10. Of these 24 documents, 15 state that they are referring to the substance “methandrostenolone” specifically and/or the particular drug named “Dianabol” (*i.e.*, the trade name for methandrostenolone), which was associated with Dr. John Ziegler and Ciba Pharmaceuticals. *Id.* at pp. 22,⁶ 37, 56 n. 47, 84, 102,

⁶ This document, apparently a List of Controlled Substances by the Drug Enforcement Agency refers to “methandienone,” which is a synonym for methandrostenolone. Exh. 9.

132, 202 n. 85, 208, 272, 292, 338, 390, 414, 433, 441, 549. Four of the documents refer to “Dianabol” the “drug” or “steroid” (singular) without identifying a chemical name. *Id.* at pp. 33, 36, 397, 581.⁷ Three of the documents include lists of anabolic steroids, “Dianabol” being among them. *Id.* at pp. 15, 16, 522.

Thus, in sum: (i) none of the documents produced by Defendants refer to a *dietary supplement* as “Dianabol” or “dianabol”; (ii) none of the documents evidences an intent to refer to anything other than the particular substance methandrostenolone; and (iii) none of the documents use the word “Dianabol” or “dianabol” to refer to a category of substances, whether drugs, supplements, or both. This evidence does not establish as a matter of law that “Dianabol” is a generic name for “dietary supplements, excluding anabolic steroids.” Doc. 160-15 at p. 54.

Further, as previously stated, “a common source of evidence on genericness is the dictionary.” *Gimix, Inc. v. JS & A Group, Inc.*, 699 F.2d 901, 905 (7th Cir. 1983) (finding “Auto Page” not generic term where not in dictionary). “Dianabol,” however, is not among the words included on dictionary.com, merriam-webster.com, en.oxforddictionaries.com, or macmillandictionary.com. (Last

⁷ While the wording of one article is somewhat unclear as to whether the author intended to describe dianabol as a single steroid or multiple steroids, *id.* at 363, review of the news article relied upon by the author for the statement clearly refers to “Dianabol, *a* steroid.” Exh. 10 (emphasis added).

checked Dec. 14, 2017). The absence of the term from these sources indicates a lack of public perception associating the word with a category goods.

As for persons in the trade, Hi-Tech and Defendants recognize the strength of Hi-Tech's DIANABOL[®] mark as a source identifier. In 2014, Defendant Clapp stated to Mr. Wheat in an email that "the brand recognition [with respect to the DIANABOL[®] and ANAVAR[®] trademarks] is massive." Exh. 8 at DSN000012.

Finally, consumer survey evidence developed by Hi-Tech revealed that over 60 percent of respondents understood "Dianabol" to be a brand name. Exh. 11 at pp. 5-6. This is sufficient to indicate that the "primary significance" of the term is a brand name, as opposed to a generic term. *Ty, Inc. v. Softbelly's, Inc.*, 353 F.3d 528, 530-31 (2003). Significantly, Defendants have submitted no survey evidence to support their claims that Dianabol is generic.

As noted above, when ruling on Hi-Tech's Second Application for Temporary Restraining Order in this case, the Court found that there was a disputed issue of material fact on the genericness issue. Doc. 82 at p. 16. The evidence gathered since then has only strengthened Hi-Tech's position, and at the very least indicated continuing disputed issues of material fact that preclude summary judgment.

D. Hi-Tech's Use of the DIANABOL[®] Trademark Does Not Fall Outside the Express Exception Noted in the Registration.

Defendants argue that the alleged detection of trace amounts of androstenedione and DHT in Hi-Tech's Dianabol[®] supplement renders the product an anabolic steroid. For the reasons discussed in Section I(A), that is not the case. Moreover, Defendants own product Winn 50 also contains androstenedione. Exh. 5. In selling its Dianabol[®] supplement, Hi-Tech is not selling anabolic steroids. Hi-Tech is selling a dietary supplement, precisely as Defendants and other entities in the dietary supplement market offering DHEA products. Hi-Tech's sales of its Dianabol[®] supplement are therefore consistent with the description of goods in its federal trademark registration.

E. Hi-Tech's Trademark Claims are Not Barred by Laches.

Years of fraudulent conduct by Defendants prohibit them from relying on the laches defense. As the United States Supreme Court has explained:

If want of due diligence by the plaintiff may make it unfair to pursue the defendant, fraudulent conduct on the part of the defendant may have prevented the plaintiff from being diligent and may make it unfair to bar appeal to equity because of mere lapse of time. Equity will not lend itself to such fraud and historically has relieved from it. It bars a defendant from setting up such a fraudulent defense, as it interposes against other forms of fraud.

Holmberg v. Armbrrecht, 66 S.Ct. 582, 584–85 (1946). Such a fraudulent defense is precisely what Defendants assert in this case.

Just three days after the Patent and Trademark Office (“PTO”) issued its final rejection of Defendants’ application to register the D-ANABOL trademark due to

the likelihood of consumer confusion with Hi-Tech's DIANABOL[®] mark, Defendant Clapp began to ingratiate himself with Mr. Wheat, providing significant and detailed information concerning the trademark infringement of others in the industry (including other's infringement of Hi-Tech's DIANABOL[®] trademark) – all while withholding information concerning the infringing activities of Defendants. Exh. 7; Exh. 8; Exh. 12. In doing so, Defendant Clapp expressly and repeatedly acknowledged that Hi-Tech's DIANABOL[®] trademark was a valuable asset worthy of protection. Exh. 8. Mr. Clapp's "friendship," however, was nothing more than a thinly-veiled attempt to distract Mr. Wheat and Hi-Tech from Defendants' own infringement. Clapp's "assistance" to Mr. Wheat was also apparently aimed at having Hi-Tech clear the market of product names that could be confused with, not only Hi-Tech's DIANABOL[®] mark, but also Defendants' D-ANABOL 25 mark.

Additionally, in June of 2011, the PTO explained to Defendants, at length, that their D-ANABOL 25 trademark was likely to be confused with Hi-Tech's registered and valid DIANABOL[®] trademark, and even provided Defendants with a copy of Hi-Tech's DIANABOL[®] registration. Exh. 7. Defendants, however, proceeded to use the D-ANABOL 25 name despite this notice that consumers were likely to confuse Defendants' product with that of Hi-Tech. Such conduct allows for an inference that Defendants intended to benefit off of Hi-Tech's trademark.

Frehling Enter., Inc. v. Int'l Select Group, Inc., 192 F.3d 1330, 1340 (11th Cir. 1999). This intent to copy and Clapp's fraudulent conduct as set forth herein, provide that the equities weigh in Hi-Tech's favor on the laches issue. *See, e.g., Baker v. Simmons Co.*, 307 F.2d 458, 466 n. 4 (1st Cir. 1962).

Not only should this Court refuse to grant summary judgment based upon laches due to Defendants' inequitable conduct, but also because they have failed to proffer evidence sufficient to eliminate any genuine issue of material fact as to when Hi-Tech allegedly should have known about Defendants' infringement. Defendants first argue that Hi-Tech should have known of D-ANABOL 25 because they had been selling it for several years, and because DSN's steroid.com website was a top hit for a Google search for "steroids." Doc. 160 at p. 18. However, Hi-Tech had no reason to search for infringing products being sold as steroids or anabolic steroids. Doc. 64-16 at ¶ 13. And, indeed, that is how Defendants' marketed their products, *i.e.*, on websites with domain names such as steroids.com, roidstore.com, oralsteroids.com, and buysteroids.com; on a webpage amounting to an encyclopedia regarding anabolic steroids; and on a website dedicated to the discussion of anabolic steroids. Exh. 13. Defendants, therefore, did not market their products within the usual, legitimate dietary supplement marketplace.

Defendants' argument regarding DSN's 2011 PTO application is similarly unavailing. First, while one of the benefits of a federal trademark registration is that the registration constitutes nationwide constructive notice of the registrant's priority of use of a mark, the law does not afford any similar benefit to trademark applications. *See* 15 U.S.C. § 1072; *see also Scientific Applications, Inc. v. Energy Conservation Corp. of America*, 436 F.Supp. 354, 359 (N.D.Ga. 1977) (finding the defendant's application to the Georgia Secretary of States for a certificate of name for an allegedly infringing service mark did not constitute constructive notice of use to the plaintiff). Second, DSN's D-ANABOL 25 application does not come up on a trademark search for "Dianabol" on the PTO website, such that Hi-Tech could have found it by reasonable search.⁸ Third, DSN filed its application in 2011, several years after Mr. Wheat applied for and registered the DIANABOL[®] trademark. *Compare* Exh. 14 *with* Doc. 160-15. And fourth, DSN's trademark application, which the USPTO promptly rejected, was never published for opposition in the Official Gazette. Exh. 14. Thus, the 2011 application, either alone or in conjunction with

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http://tmsearch.uspto.gov/bin/showfield?f=toc&state=4808%3Ay3o2k6.1.1&p_search=search&p_L=50&BackReference=&p_plural=yes&p_s_PARA1=&p_tagrepl%7E%3A=PARA1%24LD&expr=PARA1+AND+PARA2&p_s_PARA2=dianabol&p_tagrepl%7E%3A=PARA2%24COMB&p_op_ALL=AND&a_default=search&a_search=Submit+Query&a_search=Submit+Query (last checked Dec. 18, 2017)

other evidence on record, is not sufficient to establish as a matter of law that Hi-Tech knew or should have known it had a claim against Defendants without taking action. The evidence, rather, shows that Hi-Tech learned of Defendants' infringement on September 10, 2015, Exh.15; Doc. 64-16 at ¶ 11, and filed suit two weeks later. *Hi-Tech Pharm., Inc. v. Dynamic Sports Nutrition, LLC, et al.*, Case No. 1:15-cv-03393-MHC, Doc. 1, filed Sept. 28, 2015.⁹

F. Defendants Cannot Meet the High Burden to Obtain Cancellation of Hi-Tech's DIANABOL[®] Trademark.

As acknowledged by Defendants, in order to obtain cancellation of Hi-Tech's DIANABOL[®] trademark, Defendants must make the requisite showing by clear and convincing evidence. Doc. 160 at p. 19. The clear and convincing evidence burden is a "necessarily [] heavy burden, and any doubt must be resolved against the charging party." *Soverign Military Hospitaller Order ... of Rhodes & Malta v. Fla. Priory of the Knights Hospitallers ... Order*, 702 F.3d 1279, 1289 (11th Cir. 2012).

In seeking cancellation of Hi-Tech's DIANABOL[®] trademark registration under 15 U.S.C. § 1119, Defendants primarily repackage their "unlawful use" argument, which should be rejected as set forth in section I(A) herein.

⁹ The Court initially transferred this case to the Southern District of Texas, but the Texas District Court subsequently returned the case to this District. *Id.* at Doc. 32.

As for Defendants' fraud in registration argument, Defendants must demonstrate that Hi-Tech "knowingly ma[de] false, material representations of fact in connection with an application for a registered mark." *Progressive Emu Inc. v. Nutrition & Fitness, Inc.*, 655 Fed.Appx. 785, 798 (11th Cir. 2016). This includes a demonstration of "a purpose or intent to deceive the PTO in the application for the mark." *Soverign Military*, 702 F.3d at 1289. An honest misunderstanding or inadvertence is insufficient. *Id.* at 1292.

Defendants have failed to meet their heavy burden. First, Defendants identify no evidence that Mr. Wheat knew when applying for the trademark registration in 2007 that Hi-Tech's Dianabol[®] supplement might contain the trace amounts of androstenedione and DHT alleged. Second, Defendants once again presume materiality with respect to the alleged trace amounts, which is also unsupported by the record. The *de minimus*, harmless, and unavoidable amount of androstenedione detected as a result of formulating the lawful DHEA ingredient is not "material" and should not strip Hi-Tech of all rights in its incontestable DIANABOL[®] trademark. Third, Defendants' argument that Hi-Tech's DIANABOL[®] label fails to disclose the presence of DHEA is factually inaccurate as set forth above in section I(A)(2). Under these circumstances, Defendants have failed to establish either intent

to deceive or materiality by clear and convincing evidence, and their motion for summary judgment must fail.¹⁰

G. There Is a Likelihood of Confusion Between Hi-Tech's DIANABOL[®] Trademark and Defendants' D-ANABOL 25 Mark.

Courts consider the following seven factors in evaluating whether a likelihood of consumer confusion exists: (1) the type of mark; (2) the similarity of the mark; (3) the similarity of the products the marks represent; (4) the similarity of the parties' trade channels and customers; (5) the similarity of advertising media; (6) the defendant's intent; and (7) actual confusion. *Freshling Enter., Inc.*, 192 F.3d at 1335.

This Court has already found that factors (2) through (6) weigh in Hi-Tech's favor. Doc. 82 at pp. 17-19. As indicated by Defendants' failure to argue otherwise,

¹⁰ Defendants also argue that the DIANABOL[®] trademark is "inherently and fatally fraudulent due to the fact that the product 'described' as Dianabol did not, as reasonable consumers might believe, contain Dianabol." Doc. 160 at p. 20. This argument, however, does not relate to any alleged fraud on the USPTO, and Defendants have not introduced evidence that the trademark is "deceptively misdescriptive." For instance, Defendants have proffered no evidence that consumers are likely to believe the DIANABOL[®] trademark actually describes a product containing methandrostenedione (particularly in the context of the marketing and packaging for Hi-Tech's DIANABOL[®] product in the *dietary supplement market*), that any such belief would affect a consumer's decision to purchase the product, or that the public was actually deceived. *Hako-Med USA, Inc. v. Axiom Worldwide, Inc.*, 2006 WL 3760416, at *2 (M.D.Fla. 2006).

the evidence with respect to these factors has not changed. *See* Doc. 160 at pp. 21-22. This alone should preclude summary judgment on likelihood of confusion.

As for the type of mark, as set forth above, Hi-Tech's mark is not generic. Even if Hi-Tech's mark could be deemed weak, which Hi-Tech disputes, this alone is not sufficient for summary judgment. *Honeysweet Hams, Inc.*, 656 F.Supp. at 96.

The last factor, actual confusion, is not necessary to support a finding of likelihood of confusion. *E. Remy Martin & Co., S.A. v. Shaw-Ross Intern. Imports, Inc.*, 768 F.2d 1525, 1529 (11th Cir. 1985). Nevertheless, Hi-Tech has favorable evidence on this factor as well. A consumer survey commissioned by Hi-Tech found that "50% of [nutritional supplement purchasers] say D-ANABOL and DIANABOL are made by, affiliated with, or sponsored or approved by the same company based on viewing the product trademarks. ... On an unaided basis, the stated reason given most often is the similarity of the names D-ANABOL and DIANABOL." Exh. 11 at p. 3 (finding, in contrast, that only 30% of nutritional supplement purchasers saw a similar connection between the Dianabol[®] supplement and a control product). And again, Defendants have developed no evidence to rebut this finding.

II. NOT ALL OF HI-TECH'S DECEPTIVE PRACTICE AND UNFAIR COMPETITION CLAIMS RELATE TO DEFENDANTS' TRADEMARK INFRINGEMENT.

Hi-Tech agrees that the Lanham Act analysis applicable to its federal trademark claims also applies to its unfair competition and deceptive trade practice claims *to the extent those claims are based upon trademark infringement*. Hi-Tech's deceptive trade practice claim (Count VI) and its Georgia unfair competition claim (Count VII), however, relate not only to trademark infringement, but also Defendants' false advertising. Doc. 62 at ¶¶ 232, 251. As a result, to the extent those claims are based upon false advertising, they do not stand or fall with Hi-Tech's federal trademark claim. Regardless, as set forth herein, Defendants have failed to establish that they are entitled to summary judgment on Hi-Tech's trademark claims.

III. DEFENDANTS ARE NOT ENTITLED TO SUMMARY JUDGMENT ON HI-TECH'S FALSE ADVERTISING CLAIMS.

A. Unclean Hands and Other Trademark Defenses Do Not Bar Hi-Tech's False Advertising Claims.

Hi-Tech's trademark and false advertising claims are based upon distinct sets of facts. For instance, Hi-Tech's trademark infringement claim relates to the name of only one of Defendants' products, D-ANABOL 25. Doc. 62 at ¶¶ 13-51. In contrast, Hi-Tech's false advertising claims relate to Defendants' DECA 200, TREN 75, D-ANABOL 25, WINN 50, TEST 600x, CLEN, VAR 10, and Pituitary Growth Hormone products. *Id.* at ¶¶ 52-172. Defendants market this much larger group of products as though they are anabolic steroids, prescription drugs, or their equivalent,

and make a multitude of false and misleading advertising claims that their products have certain physical effects. *Id.* Hi-Tech's false advertising claims are therefore based upon a broader set of Defendants' products and much broader advertising practices by Defendants than Hi-Tech's trademark claims. Defendants' trademark defenses simply are not sufficient to address all of the products and advertising statements at issue in Hi-Tech's false advertising claims.

Further, Defendants again fail to address the elements of the unclean hands defense in the false advertising context. For example, Defendants fail to establish that any alleged wrongdoing by Hi-Tech "directly relates" to Hi-Tech's false advertising claims against Defendants, and that Defendants were personally injured by the conduct. *Bailey*, 776 F.3d at 801. Defendants also again fail to demonstrate the elements of a false advertising claim, much less establish that there is no genuine issue of material fact as to Hi-Tech's advertising. *Wika Instrument I, LP*, 2015 WL 11199059, at *8; *Immuno Vital*, 49 F.Supp.2d at 1358-59.

B. A Reasonable Jury Could Conclude Defendants Have Engaged in False Advertising.

In arguing that they are entitled to summary judgment on Hi-Tech's false advertising claims, Defendants merely recite the elements of a false advertising claim followed by a single sentence arguing that "Hi-Tech has not offered and cannot offer proof of the required elements." Doc. 160 at p. 24. Defendants' Motion

includes no further contentions or argument. Thus, Defendants’ Motion regarding Hi-Tech’s false advertising claims falls far short of Defendants’ heavy burden on summary judgment. *See Hickson*, 357 F.3d at 1259-60. Moreover, Hi-Tech has developed un rebutted evidence precluding summary judgment in this case.

As acknowledged by Defendants, the elements of a false advertising claim are (1) the advertisements of the opposing party were false or misleading; (2) the advertisements deceived, or had the capacity to deceive, consumers; (3) the deception had a material effect on purchasing decisions; (4) the misrepresented product or service affected interstate commerce; and (5) the movant has been – or is likely to be – injured as a result of the false advertising. *Id.* at 1260.

Defendants’ advertising includes claims such as “pack on pounds of high quality dense muscle”; “add extreme strength and hardness with little weight gain”; “dramatically enhance muscle endurance and stamina”; and “help athletes increase speed and strength while building powerful lean muscle.” Exh. 17 at ¶¶ 44, 57, 58, 72. Defendants further represent that their products “mimic anabolic steroids,” and that Defendants enable consumers to “Buy Steroids Legally Without a Prescription.” Exh. 13 at pp. 8, 13. These statements, along with countless other similar statements by Defendants, are false and misleading.

For example, the record reflects the following: (1) expert testimony by Dr. Marvin Heuer explaining why the consumption of Defendants' products could not cause the physical effects advertised, and why Defendants' advertising is otherwise false and misleading, Exh. 17; (2) no expert or scientific substantiation supporting Defendants' advertising claims;¹¹ (3) several instances of actual consumer confusion between Defendants' products and anabolic steroids;¹² (4) an internal memo sent by Clapp saying that he wanted Defendants' online advertising to "trick the viewer into thinking that ... our bottles are real steroids," Exh. 19; and (4) a consumer survey finding that substantial numbers of respondents understood Defendants' to be advertising anabolic steroids and incorrectly believed the products would have the physical effects advertised, Exh. 20 at pp. 20-25.

Defendants' advertising claims are material because they misrepresent "an inherent quality or characteristic of the product." *Johnson & Johnson Vision Care, Inc. v. 1-800 Contacts, Inc.*, 299 F.3d 1242, 1250 (N.D.Ga. 2002). For example, Defendants create the false and misleading impression that their products are

¹¹ Exh. 18, Clapp Dep. at 42:1-43:4; 44:5-17; 52:1-53:8; 57:11-21; 60:14-61:13; 70:3-19; 73:14-74:1; 108:4-23; 115:3-23; 116:1-117:2; 117:7-119-6; 119:1-120:25; 125:2-16; 126:7-127:15.

¹² *Id.* at 133:21-134:11; Exh. 16 at DEF006194, 6920, 6921, 6949, 6957, 6972, 6990, 6933, 7025, 7032, 7801, 7083, 7087, 7088. 7091, 7117, 7129, 7130, 7139, 7142, 7149, 7182, 7189.

anabolic steroids or their equivalent, as well as the efficacy of those products. *See Osmose, Inc. v. Viance, LLC*, 612 F.3d 1298, 1319 (11th Cir. 2010) (finding safety and efficacy claims material). Additionally, consumer survey evidence shows that claims concerning a reduction in body fat, increased muscle size, and increased muscle strength—such as those made by Defendants—would make at least two-thirds of respondents more likely to purchase a product. Exh. 20 at p. 25.

There is also no dispute that Defendants advertised their products on the internet and sold and shipped their products to consumers in various states around the country, *i.e.*, in interstate commerce. Exh. 13; Exh. 16; Doc. 67 at ¶ 271.

Finally, Hi-Tech has been or is likely to be injured by Defendants’ false advertising. Defendants’ fraudulent practices are generating the sale of significant numbers of unit sales each year, and earning them extensive revenue. Exh. 21; Exh. 22. This is a significant impact on the consumer market, and therefore harms, and is likely to harm, Hi-Tech as a direct competitor. Making matters worse, as demonstrated by survey evidence, Defendants’ trademark infringement creates a false association between Defendants’ advertising and products and Hi-Tech, thereby leading to an association between Hi-Tech and Defendants’ wholly ineffective, false “steroid” products. Exh. 11 at p. 3.

IV. DEFENDANTS ARE NOT ENTITLED TO SUMMARY JUDGMENT ON HI-TECH’S RICO CLAIMS.

Defendants' Motion concludes that Hi-Tech's Georgia RICO claims must fail because the "mail and wire fraud allegations are simply restatements of its trademark claims..." Doc. 160 at pp. 24-25. Defendant makes this argument in two sentences with no analysis of the law or facts. In doing so, Defendants' conveniently ignore that Hi-Tech's RICO claims are not based solely upon trademark issues, but rather a widespread fraudulent scheme, of which Defendants' infringement was but a part.

Defendants' unlawful scheme involved the deception of consumers by way of false and misleading product claims, and by creating a false association between Defendants' products and Hi-Tech. Doc. 62 at ¶¶ 266-267. In doing so, Defendants intentionally defrauded Hi-Tech out of sales and profits through their diversion and confusion of customers, and concealed their fraudulent scheme with years of deceptive and distracting correspondence to Mr. Wheat. *Id.* at ¶ 273. Indeed, the record indicates that Defendants viewed Hi-Tech, a dietary supplement company enjoying "massive" brand recognition, as a primary competitor and threat. Exh. 8. The record is replete with examples of Defendants using the mail and wires in furtherance of this scheme to defraud Hi-Tech, and Defendants' concealment thereof. *Id.*; Exh. 13; Exh. 16; Doc. 67 at ¶ 271. Each one of these instances constitutes a predicate act under Georgia RICO. O.C.G.A. § 16-14-3(5)(C).

Civil RICO provides a remedy for such fraudulent marketplace conduct. *See, e.g., Allen v. Hones*, 269 Ga. App. 607, 611 (2004) (the knowing distribution of fraudulent promotional materials can underlie a civil claim under Georgia RICO); *InterAgency, Inc. v. Danco Fin. Corp.*, 203 Ga. App. 418, 427 (1992) (same);¹³ *SJ Advanced Tech. & Mfg. Corp. v. Junkunc*, 627 F.Supp. 572, 576 (N.D.Ill. 1986) (“Nothing blocks an injured competitor from calling on civil RICO.”); *see also Bridge v. Phoenix Bond & Indem. Co.*, 553 U.S. 639, 661 (2008) (misrepresentations to third parties can form predicate acts for RICO claims); *Quorum Health Res., LLC v. Hospital Auth. of Wayne County, Georgia* 2010 WL 11537682, at *13 (S.D.Ga. July 12, 2010) (predicate acts of mail and wire fraud can be shown by “proof of a routine practice of using the wires or mails to accomplish a business end”).

This is not, therefore, a RICO case based upon nothing but run of the mill trademark claim as argued by Defendants. Defendants, rather, engaged in an elaborate and multi-faceted fraud, successfully earning them significant funds.

CONCLUSION

Wherefore, Hi-Tech Pharmaceuticals, Inc. respectfully requests that this Court deny Defendants’ Motion for Summary Judgment in its entirety.

¹³ *See also InterAgency*, 203 Ga. App. at 419 (explaining how Georgia RICO is “significantly broader than its federal counterpart”).

Dated: December 18, 2017

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that, on this 18th day of December 2017, I have electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system, which will automatically send e-mail notification of such filing to all attorneys of record.

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